

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 07 MAY 2004

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Applicant's or agent's file reference PCT-6932	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IT 03/00007	International filing date (day/month/year) 13.01.2003	Priority date (day/month/year) 15.01.2002
International Patent Classification (IPC) or both national classification and IPC C07D209/08		
Applicant SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 29.07.2003	Date of completion of this report 06.05.2004
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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/IT 03/00007**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-88 as originally filed

Claims, Numbers

1-9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-4,6-9 (all part)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 1-4,6-9 (all part) are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5
	No: Claims	1-4,6-9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

2. Citations and explanations

see separate sheet

III. Non-establishment of opinion

In view of the lack of support and disclosure of the present claims, the search examiner was only able to perform a meaningful search for the compounds of formula I wherein Ar is optionally substituted phenyl, naphthyl, 1-indolyl, 3-indolyl, 2-pyridyl or pyridinium; $(Z)_f(CH_2)_m(Q)_h$ is CH_2CH_2O , $CH_2CH_2CH_2O$, $NH(C=O)O$, $CH_2NH(C=O)O$ or $CH_2NH(C=O)$; the phenylene moiety is a p-phenylene, m-phenylene or a m-phenylene group substituted by a methoxy group and the $(A)_n(R1)COY$ group represents a thiazolidine-2,4-dione or a carboxylic acid or ester as defined in claim 1 (see International Search Report for details). The following examination is based on search subject matter only.

V. Reasoned statement

Novelty

All the documents in the search report disclose general formulae overlapping with present formula (I) and/or specific compounds falling within present formula (I) (see International Search Report for details). For example, the general formula disclosed in JP2000344748 overlaps with present formula (I) and the 7 specific compounds listed in the CAPLUS abstract annexed to the search report fall within the scope of this formula. The same is true for general formula (I) of WO99/62871 and examples 26b and 99-100, general formula (I) of EP-A-0 008 203 and e.g. example 13 and general formula (I) of EP-A-0 930 299 and examples 57 and 58. The compounds described in these documents are alleged to be useful in the treatment of diabetes.

Claims 1-4 and 6-9 do not fulfil the requirements of Article 33(2) PCT.

Inventive step

No inventive step can be acknowledged for subject matter which is not novel. The compounds of claim 5 are not specifically disclosed in the documents cited in the International Search Report. However, they fall within the scope of the cited documents. For example, compound xxi falls within the scope of general formula (I) of EP-A-0 008 203 and is a homologue of example 2 of this document. Compound xxxv falls within the scope of general formula (I) of EP-A-0 930 299 and is a closely related analogue of example 58 of this document. It would be obvious for the skilled man wishing to solve the technical problem of providing hypolipidemic and hypoglycemic compounds for use in the treatment of diabetes

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to select specific compounds already generically disclosed as having this activity in e.g. EP-A-0 008 203 and EP-A-0 930 299. For this reason claim 5 is not considered to be inventive.

Claims 1-9 do not fulfil the requirements of Article 33(3) PCT.

Industrial applicability

Claims 1-9 fulfil the requirements of Article 33(4) PCT.